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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/07/07 08/16/08 CAPUT

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DEPARTMENT  
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EXAMINER

BASIN

ART UNIT

1848

PAPER NUMBER

DATE MAILED:

12/19/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/077,817**

Applicant(s)  
**Caput et al**

Examiner  
**Nirmal. S. Basi**

Group Art Unit  
**1646**



☒ Responsive to communication(s) filed on Sep 5, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-43 is/are pending in the application.

Of the above, claim(s) 5-36 and 38 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 37, and 39-43 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-43 are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. A restriction requirement was made in the prior Office Action, mailed August 31, 2000.

During a telephone conversation with Paul Dupont on September 1, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-4, 37 and 39-43 drawn to polypeptide comprising SEQ ID NO:2. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-36 and 38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

2. The Preliminary Amendments filed 9/14/98, 9/1/99 and Amendment filed 10/21/99 have been entered.
3. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 10/25/00 have been approved.

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The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

### **INFORMATION ON HOW TO EFFECT DRAWING CHANGES**

#### **Correction of Informalities -- 37 CFR 1.85; 1097 O.G. 36**

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### **Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

#### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

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### *Specification*

4. This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Please note the following errors in particular:

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Application does not contain a title of the Invention.

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Application does not contain a Brief Description of the Several Views of the Drawing(s).

Application contains a partial duplicate page 46, which must be canceled. The partial duplicate page 46, contains lines 1-21.

Appropriate correction is required.

5. The drawings objected to because each Figure must be described separately in the Brief Description of the Drawings. For example: Figure 2 should be labeled Figure 2A, 2B and 2C (presently labeled as FIG.2a, FIG.2a(continuation); Figure 7 should be labeled Figure 7A, 7B and 7C (presently labeled as FIG.7a, FIG.7a(continuation), FIG.7b; Figure 8 should be labeled Figure 8A, 8B and 8C (presently labeled as FIG.8a, FIG.8(continuation) and FIG. 8 (suite); or the equivalent, as required by 37 C.F.R. § 1.84 (u)(1).

Appropriate correction is required.

6. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825.

Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO.

Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequence in claim 3 (VRCVTL) has no reference to a SEQ ID NO: . Sequence on page 24, line 11 (WSXWS) no reference to a SEQ ID NO: . Further sequences referred to as "SEQ ID No." in claims 1-4 must be referred to as "SEQ ID NO:." Compliance with sequence rules is required.

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### ***Claim Objection***

7. Claims 37, 40, 42 and 43 objected to as being in improper dependent form because a claim cannot depend on a non elected claim, directly or indirectly. It is suggested, to overcome the objection, claims 37, 40, 42 and 43 be rewritten to include all of the limitations of the base claim and any intervening claims or have dependency on elected claims. Further claims 40 and 42 are directed to IL-13R $\alpha$  whereas the elected invention of Group 1 is directed to IL-13R $\beta$ . It is suggested claims 40 and 42 be amended to correspond to the elected Invention of Group 1.

### **Claim Rejections - 35 USC § 101**

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 39-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 39-43 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Amending the claim to recite "a process or a method" will obviate this rejection.

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**Claim Rejection, 35 U.S.C. 112, second paragraph**

9. Claims 1-4, 37 and 39-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clear if the polypeptide comprises only the limitations of a) or b), or comprises the limitations of a) and b) together so as to allow the metes and bounds of the claim to be determined. Further the claim is indefinite because it is not clear what is "any biologically active sequence derived from SEQ ID No:2". The biological activity and the particular polypeptide sequences containing said biological activity have not been defined so as to allow the metes and bounds of the claim to be determined.

Claim 3 is indefinite because it is not clear which 8 C-terminal residues are substituted so as to allow the metes and bounds of the claims to be determined. It is suggested the residues be identified by amino acid number. Further it is not clear if the "variant" contains other substitutions, deletions or additions in conjunction to the 8 C-terminal residues which are substituted by the residues VRCVTL.

Claims 1 and 4 indefinite for the following reasons: A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where



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broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation of "any biologically active sequence derived from SEQ ID No.2 and also recites the narrower limitation of SEQ ID No.2; claim 4 recites the broad recitation "stretching up to residue 243", and the claim also recites "preferably up to residue 337" which is the narrower statement of the range/limitation.

Claim 4 is further indefinite due to the recitation "a soluble form stretching up to". It is unclear what form of the polypeptide is being claimed, as it is unclear what physical characteristics of a polypeptide are indicated by the term "stretching" and what is a "soluble form".

Claims 39-43 are indefinite because said claims provide for the use of a polypeptide, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 39 and 40 is indefinite because it is not clear what "activity" of the IL-13R $\beta$  is being modulated and how such is screened so as to allow the metes and bounds of the claim to be determined.

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Claims 41 and 42 are indefinite because it is not clear what products are capable of modulating the activity of IL-13R $\beta$  (no structure provided), what "activity" of the IL-13R $\beta$  or IL-13R $\alpha$  they modulate and how said products are manufactured so as to allow the metes and bounds of the claim to be determined.

Claim 43 is indefinite because it is not clear what product has IL-13 antagonizing effect (no structure provided), what effect of IL-13 is being antagonized and how said products are synthesized so as to allow the metes and bounds of the claim to be determined.

Claims 2 and 37 are rejected for depending upon an indefinite base (or intermediate) claim and fail to resolve the issues raised above.

***Claim Rejections - 35 USC § 101 and 35 USC § 112, 1st paragraph***

The following is a quotation of 35 U.S.C. 101:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 4 37, 39-43 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

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A "specific utility" is a utility that is specific to the subject matter claimed, as opposed to a "general utility" that would be applicable to the broad class of the invention. A "substantial utility" is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. A "well established utility" is a utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. A "well established utility" must also be specific and substantial as well as credible.

Based on the record, there is not a "well established utility" for the claimed invention.

Applicant has asserted utilities for the specifically claimed invention of claims 1, 3, 4 37, 39-43.

The claims are drawn to isolated polypeptide comprising:

- a) Any biologically active polypeptide sequence derived from SEQ ID NO:2
- b) truncated form of the polypeptide consisting of residues 1-343 and residues 1-337 of SEQ ID NO:2
- c) a substituted polypeptide in which the last 8 C-terminal residues of SEQ ID NO:2 are substituted with the residues VRCVTL
- d) pharmaceutical composition comprising a) and/or b) as the active ingredient

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e) use of composition a) and/or b) in screening assay, for manufacture of products capable of modulating activity of IL-13 $\beta$  and for synthesis of a medicinal product with IL-13 antagonizing effect.

The specification discloses: I) a distinct polypeptide (IL-13 receptor  $\beta$ ) sequence of SEQ ID NO. 2 which binds IL-13, ii) truncated form of the polypeptide consisting of residues 1-343 and residues 1-337 of SEQ ID NO:2, and iii) a substituted polypeptide in which the last 8 C-terminal residues are substituted by VRCVTL. Instant disclosure, nor prior art provide any data or suggest that the products ii) and iii) have any biological activity.

The specification discloses that IL-13 regulates anti-inflammatory and immunoregulatory activities and that this cytokine has pleiotropic effects. IL-13 binds IL-13 receptor  $\beta$  (IL-13R $\beta$ ) and may be useful in treatment of autoimmune, tumor and viral pathologies. The specification discloses that administration to a patient IL-13R $\beta$  or a biological active fragment thereof may be used in a method for modulating the immunological reactions mediated by IL-13 (page 4). Further disclosed is IL-13R $\beta$  may be used diagnostic assays and isolation of ligands specific for IL-13R $\beta$  (page 12).

In light of the specification the skilled artisan cannot determine the structure of the biologically active sequences derived from the disclosed "any biologically active sequence derived from SEQ ID NO:2" (a above) and the disclosure nor prior art provide evidence that the products in b) and c) above have any biological activity. Further no evidence is provided that the afore

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mentioned products can be used as pharmaceutical composition, medicament or in any other methods disclosed in d) and e) above.

The utilities asserted by Applicant are not specific or substantial. Since no specific function of the polypeptide of a), b) and c) disclosed above is known, and the hypothesized function of said polypeptides in d) and e) above is based entirely on conjecture, the asserted utilities are not specific to instant polypeptide, but rather are based on SEQ ID NO:2. Neither the specification nor the art of record disclose the protein of SEQ ID NO:2 or fragments thereof useful to identify drugs that affect said protein and modulate its activity. Similarly, neither the specification nor the art of record disclose any instances where disorders can be effected by interfering with the activity biological active derivatives of SEQ ID NO:2. Thus the corresponding asserted utilities are essentially methods of using the polypeptide of a), b) and c) disclosed above to identify disease states or assays associated with IL-13R $\beta$  polypeptide disfunction and as targets for drug discovery. Therefor the asserted utilities are essentially methods of testing for or for potentially treating unspecified, undisclosed diseases or conditions, which does not define a "real world" context of use. Treating or testing for compounds that interact with the polypeptide of a), b) and c) disclosed which may be implicated in an unspecified, undisclosed disease or condition would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Since neither the specification nor the art of record disclose any activities or properties that would constitute a "real world" context of use for the claimed polypeptides comprising variants disclosed above, further experimentation is

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necessary to attribute a utility to the claimed polypeptides and derivatives thereof. See *Brenner v. Manson*, 383 U.S. 519, 535–36, 148 USPQ 689, 696 (1966) (noting that “Congress intended that no patent be granted on a chemical compound whose sole ‘utility’ consists of its potential role as an object of use-testing”, and stated, in context of the utility requirement, that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”).

11. Claims 1, 3, 4 37, 39-43 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Since neither the specification nor the art of record disclose any activities or properties that would constitute a “real world” context of use for the claimed derivative recited as a), b) and c, above, further experimentation is necessary to attribute a utility to the claimed polypeptides and fragments thereof.

Further, claims 37 and 42 are rejected based on the failure of the specification to enable one of skill in the art to make and/or use the pharmaceutical composition encompassed by the claim. The pharmaceutical composition comprising the polypeptide set forth in SEQ ID NO:2 or a derivative thereof infers a drug or medication with therapeutic activity. The specification does not reasonably enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim without undue experimentation. Factors to be considered in determining whether undue experimentation

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is required are summarized in *In re Wands* (8 USPQ2d 1400 (CA FC 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented. The term "pharmaceutical" implies a treatment of a disease. Neither the specification nor the prior art provide sufficient guidance as to what specific diseases could be treated by administering a "pharmaceutical composition" comprising the polypeptide set forth in SEQ ID NO:2 or a derivative thereof. Attempting to identify a disease treatable by such a "pharmaceutical composition" would constitute undue experimentation. Therefore one of skill in art would have to identify a disease treatable by said "pharmaceutical composition", determine effective compositions, determine effective doses to achieve the intended purpose, determine routes of effective administration, determine if the "pharmaceutical composition" can reach its target tissue without degradation and determine if it has a therapeutic effect, all of which would constitute undue experimentation. Therefore, the unpredictability to achieve all the aforementioned goals and the lack of guidance provided in the specification, the disclosure fails to enable one of skill in the art how to make and/or use the "pharmaceutical composition" encompassed by the claims 37 and 42.

12. Claims 1, 4, 37, 39-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written

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description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to isolated polypeptide comprising:

- a) Any biologically active polypeptide sequence derived from SEQ ID NO:2
- b) polypeptide comprising SEQ ID NO:2
- c) pharmaceutical composition comprising a) and/or b) as the active ingredient
- d) use of composition a) and/or b) in screening assay, for manufacture of products

capable of modulating activity of IL-13 $\beta$  and for synthesis of a medicinal product with IL-13 antagonizing effect.

The specification discloses: i) a distinct polypeptide (IL-13 receptor) sequence of SEQ ID NO. 2, ii) truncated form of the polypeptide consisting of residues 1-343 and residues 1-337 of SEQ ID NO:2, and iii) a substituted polypeptide in which the last 8 C-terminal residues are substituted by VRCVTL. Instant disclosure, nor prior art provide any data or suggest that the products ii) and iii) have any biological activity. The instant disclosure of one distinct polypeptide which may contain a 6 amino acid substituted C-terminus does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length, truncated, fusion polypeptides and variants thereof, and pharmaceutical compositions comprising said polypeptides and use of said polypeptide in c) and d) above. A description of a genus of polypeptides may be achieved by means of a recitation of a



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representative number of polypeptides, defined by an amino acid sequence, falling within the scope of the genus or of a recitation of structural and functional features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polypeptides. There is no description of the conserved regions which are critical to the structure and function of the genus claimed or which sequences may be biologically active and what is that biological activity. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and predict their use in c) and d) above. Further no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

The specification further fails to identify and describe the regulatory regions essential to the function of the claimed invention, which are required since the claimed invention currently encompasses the full length, truncated, fusion polypeptides and variants thereof. Since the disclosure fails to describe the common attributes or characteristics that identify members of the

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genus, the disclosure of the ability to have any biological active sequence derived from SEQ ID NO:2, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

An adequate written description of a protein, requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, an adequate written description of a protein is more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the protein itself. Accordingly, the specification does not provide a written description of the invention of claims 1, 37, 39-43

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Sigma.

Claim 1 is drawn to any polypeptide which is biologically active and comprises a sequence derived from SEQ ID NO:2.

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Sigma discloses biologically active polypeptides comprising an amino acid sequence which can be derived from SEQ ID NO:2. For example, on page 1081, item A4777, is an active polypeptide comprising amino acids which occur in SEQ ID NO:2 and, therefore, can be derived from SEQ ID NO:2.

14. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Vita et al. (reference B on PTO form 1449).

Claims 1 and 2 are drawn to a purified polypeptide comprising an amino acid sequence of SEQ ID NO:2.

Vita et al. discloses IL-13  $\beta$  receptor polypeptide purified from solubilized cells by electrophoresis (see for example Fig 4, panel B). Vita et al. do not disclose the sequence of said polypeptide, however, absent evidence to the contrary, it would be expected that the purified polypeptide disclosed by Vita et al. would inherently comprise the amino acid sequence SEQ ID NO:2. This is evidenced by the fact that the polypeptide disclosed by Vita et al. posses the same activity as the instant SEQ ID NO:2, with respect to IL-13 crosslinking, is from the same organism as the instantly claimed polypeptide (human), and has an apparent molecule weight comparable to that disclosed in the instant specification (approximately 70kD).

No claim is allowed

#### **Advisory Information**

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**Advisory Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi  
Art Unit 1646  
December 17, 2000

  
YVONNE EYLER, PH.D  
PRIMARY EXAMINER